DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 13 1999

NDA 12-151/S-035, S-056, S-059 S-056, S-059
NDA 12-616/S-037, -058, S-061 S-058, S-061

Searle
Attention: Ms. Ingrid Hoos
4901 Searle Parkway
Skokie, IL 60077

Dear Ms. Hoos:

We acknowledge the receipt of your October 13, 1998 submissions containing final printed labeling in response to our July 30,1997 (NDA 12-151) and November 13,1997 (NDA 12-616) letters approving your supplemental new drug applications for Aldactone (spironolactone) Tablets (NDA 12-151/S-035 and S-056) and Aldactazide (spironolactone with hydrochlorothiazide) Tablets (NDA 12-616/S-037 and S-058).

We have reviewed the labeling that you submitted in accordance with our July 30,1997 (NDA 12-151) and November 13, 1997 (NDA 12-616) letters, and we find it acceptable.

Please refer to your supplemental new drug applications dated October 13, 1998 submitted to the same applications.

These supplemental new drug applications provide for final printed labeling revised to include "vasculitis" under the **Hypersensitivity** subsection of the **ADVERSE REACTIONS** section of the labeling.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the final printed labeling included in your October 13, 1998 submission. Accordingly, these supplemental applications are approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Mr. Gary Buehler
Regulatory Health Project Manager
(301) 594-5332

Sincerely yours,

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research